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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/675,283	09/30/2003	Stephen Allen Goldman	CM2653CL	5474

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EXAMINER	
WU, IVES J	

ART UNIT	PAPER NUMBER
1713	

DATE MAILED: 12/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/675,283	GOLDMAN ET AL.	
	Examiner	Art Unit	
	Ives Wu	1713	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 October 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8, 10-14 and 16-18* is/are rejected.

7)☒ Claim(s) *9 and 15* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

(1). The applicant's Remarks filed on October 28, 2005 has been received and acknowledged with the following results.

The rejection for claims 1-18 in the prior Office Action dated on July 19, 2005 is withdrawn in response to the applicant's Remarks filed on October 28, 2005.

A new ground of rejection for claims 1-18 is presented as following.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

(2). **Claims 1-8, 10-14** and **16-18** are rejected under 35 U.S.C. 103(a) as being unpatentable over Coles et al (US006613030B1) in view of Brandt et al (US004654039).

As to the component of cross-linked hydrophilic polymer from 10 – 60 wt % in a hydrogel adhesive in independent claim 1, Coles et al disclose as cited: The adhesive is thus typically formed by polymerizing an aqueous reaction comprising from 5 to 50 wt % of hydrophilic monomer, Col. 14, line 25-28; According to the patentee's invention the polymer component of the adhesive can be physically or chemically crosslinked in order to form 3 dimensional matrix, Col. 7, line 21-23.

As to the component of water-soluble non-ionic humectant from 5 to 80 wt % in a hydrogel adhesive in independent claim 1, Coles et al disclose as cited: The compositions according to the invention generally comprise, in addition to a crosslinked polymeric network, an aqueous plasticizers are generally used in the invention to control adhesive properties. The aqueous plasticizing medium optionally additionally comprises a polymeric or non-polymeric polyhydric alcohol (such as glycerol), Col. 11, line 44-51; The aqueous reactive mixture preferably comprises from 10 to 50 % of plasticizer (other than water) by weight of the mixture, Col. 11, line 55-57; Whilst the presence of glycerol or other polyhydric alcohols in other reported formulations has been quoted to provide humectant properties to the hydrogel, Col. 7, line 67 – Col. 8, line 3.

As to the component of water from 10 to 85 wt % in a hydrogel adhesive in independent claim 1, Coles et al disclose as cited: The adhesive is thus typically formed by polymerizing an aqueous reaction comprising 3 to 40 % by weight of the reaction mixture, of water, Col. 14, line 25-34.

As to the component of crosslinked hydrophilic polymer having weak acid monomer units at least 50 mol%, at least 50 mol % in their acidic form, less than 30 mol% of all monomer

units in salt form in independent claim 1, Coles et al **teach** additional monomers to be acrylic acid or salt or ester thereof (Col. 11, line 41-42). Coles et al **do not teach** the amount of acrylic acid to be at least 50 mol% in hydrophilic polymer, at least 50 mol% in its weak acid form, and less than 30 mol% of all monomers in salt form in the crosslinked hydrophilic polymer.

However, Brandt et al **teach** a hydrogel-forming polymer prepared from polymerizable, unsaturated, acid-containing monomers. Such monomers include the olefinically unsaturated sulfonic acids and olefinically unsaturated carboxylic acids (Col. 5, line 1-7). The hydrogel-forming polymer materials must prepared at least 50 to 99.99 mole % from acid group-containing monomers (Col. 5, line 33-39) which include the embodiment when the amount of weak acid (olefinically unsaturated carboxylic acids) is at least 50 mole %. Furthermore, such hydrogel-forming polymer composition contains at least 25 mol% of monomers which is to form the polymer are acid group-containing monomers which have been neutralized with a salt-forming cation including alkali metal (Col. 7, line 25-38) which also includes the embodiment when the amount of weak acids is at least 50 mol% in its acid form with the total salt form acid monomers at most 30 mol% in the hydrophilic polymer composition.

The advantages of using at least of 50 mol% of acid group-containing monomers such as olefinically unsaturated carboxylic acids, olefinically unsaturated sulfonic acid monomers and at least 25 mol% of acid group-containing monomers are in its salt form of an alkali metal is to obtain particular combination of gel volume, gel strength and extractable polymer content characteristics for a particular extent of neutralization (Col. 7, line 39-56).

Therefore, it would have been obvious at time the invention was made to use at least 50 mol% of acid group-containing monomers, and at least 25 mol% of acid monomers in its salt

form from teaching of Brandt et al for the hydrophilic polymer component in the hydrogel adhesive composition of Coles et al in order to obtain the aforementioned advantages.

As to acidic value of weak acid having a pKa above 3 in independent claim 1, the weak acid such as acrylic acid is 4.25 pKa (page 8-48, CRC Handbook of Chemistry and Physics, 85th ed).

As to the component of hydrophilic polymer in independent claim 1, in view of substantially identical polymer compositions disclosed by combined teaching of Coles et al and Brandt et al, and by applicant. It is the examiner's position to believe that the polymer disclosed by combined teaching of Coles et al and Brandt et al would inherently possess the hydrophilicity phase in the hydrogel composition. Since USPTO does not have proper means to conduct the experiments, the burden now is shifted to the applicants to prove otherwise. *In re Best, 562* F.2d 1252, 195 USPQ 430 (CCPA 1977).

As to the elastic modulus at a temperature of 25 °C, G'_{25} (1 rad/sec), ranging from 2000 Pa to 6000 Pa in independent claim 1, Coles et al disclose: According to the invention there is provided a bioadhesive composition characterized in that it has: (ii) an elastic modules at 1 rad/s of from 700 Pa to 15,000 Pa, Col. 8, line 21-24; Typically the elastic modulus is measured over a range of 0.01-100 rad/s at a given temperature. For skin applications the appropriate temperature is 37 °C, Col. 8, line 34-37. Although the elastic modulus of Coles et al is measured at 37 °C, it would include the range of 2000 Pa –6000 Pa if hydrogel adhesive disclosed by the combined teaching of Cole et al and Brandt et al is measure at 25°C in view of substantially identical polymer, hydrogel composition disclosed by combined teaching of Coles et al and Brandt et al, and by applicant. Since USPTO does not have proper means to conduct experiments, the burden

of proof is now shifted to the applicant to establish the difference. *In re Best,* 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

As to the limitations of **dependent claims 2, 3** and **4**, the broad disclosure of acid group-containing monomers by Brandt et al is at least 50 to 99.99 mole % including the weak acid monomers to be at least 80 mole %. The broad disclosure of salt form containing monomers by Brandt et al is at least 25 mol% from the acid group-containing acid monomers including the weak acid monomer units in an acidic form of at least 70 mol%. Furthermore, Brandt et al disclose the olefinically unsaturated cayboxylic acids including acrylic acids, methacrylic acids, itaconic acid, citraconic acids (Col.5, line 8-19).

As to limitation of dependent 5 & 6, Coles et al disclose as cited: Coles et al disclose as cited: The aqueous plasticizing medium optionally additionally comprises a polymeric or non-polymeric polyhydric alcohol (such as glycerol), Col. 11, line 49-51.

As to the limitation of dependent claim 7, in view of substantially identical hydrogel composition disclosed by combined teaching of Brandt et al and Coles et al, and by applicant, it is examiner position to believe that the hydrogel of Coles et al and Brandt et al would inherently possess the Saline Absorption Rate which is less than 2.5×10^{-3} g/cm^2/sec$^{0.5}$. Since USPTO does not have proper means to conduct experiments, the burden of proof is now shifted to the applicant to establish the difference. *In re Best,* 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

As to the ratio of elastic modulus/viscous modulus to be in the range 0.15 to 0.65 in dependent claim 8, Coles et al disclose as cited: G_{37}' (1 rad/sec) is in the range 500 Pa – 20,000 Pa preferably 700 Pa to 15,000 Pa, most preferably 1000 Pa to 10,000 Pa. G_{37}" is in the range

100 Pa to 15,000 Pa, preferably 100 Pa to 10,000 Pa, most preferably 300 Pa to 5000 Pa. Therefore the ratio of G_{37}'= 500 Pa/G_{37}" =1000 Pa is 0.5 which is in the limitation of the claim 8.

As to the peel strength of hydrogel adhesive on dry skin ranging from 0.3 N/cm to 3.0 N/cm in dependent claim 8, Coles et al disclose the quantitative method to determining average peel force required to remove a skin at a specified peel angle and speed. However, Coles et al do not provide test results of samples. In view of substantially identical hydrogel composition disclosed by combined teaching of Coles et al and Brandt et al, and by applicant, it is examiner position to believe that the hydrogel taught by Coles et al and Brandt et al would inherently possess the Peel strength on dry skin ranging from 0.3 N/cm to 3.0 N/cm. Since USPTO does not have proper means to conduct experiments, the burden of proof is now shifted to the applicant to establish the difference. *In re Best,* 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

As to the limitation of dependent claim 10, Coles et al disclose as cited: According to the present invention the adhesive as described herein may also find application to attach other articles to the skin, Col. 18, line 36-38; The word "skin" according to the present invention (prior art) does not relate to the specific derma of the user but includes the mucous tissue as well as the hair which is typically found in the genital region, Col. 4, line 22-25.

As to the limitation of dependent claim 11, Coles et al disclose: The adhesive may also in addition find application to attach articles to the skin such as ostomy devices, Col. 18, line 67; Because the hydrogel adhesive disclosed by combined teaching of Coles et al and Brandt et al is substantially identical to the hydrogel adhesive in the applicant's claim 1, it will be useful in a disposable human waste management by being disposed on a wearer facing surface as well, the intended use must result in a manipulative difference as compared to the prior art. See In re

Casey, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and In re Otto, 312 F.2d 937,939,136 USPQ 458,459 (CCPA 1963).

As to the limitation of dependent claim 12, Coles et al disclose as cited: The disposable absorbent article is described below by reference to a sanitary napkin, Col. 16, line 45-46; The sanitary napkin has two main surfaces, a body contacting or wearer facing surface on which the adhesive is applied and a garment facing or contacting surface, Col. 16, line 64-66.

As to the limitation of dependent claim 13, Coles et al disclose as cited: The adhesives may for example find utility to adhere functional articles which adhere to the skin such as cosmetic or pharmaceutical delivery articles which provide a substance to the skin such as skin treatment substances, cream, lotions, hormones, vitamins, deodorants, drugs; cosmetic or pharmaceutical delivery articles provide a substance to emanate away from the skin, Col. 18, line 38-44; The adhesive may also in addition find application to attach articles to the skin such as protective articles such as clothing, prosthesis, cold wraps thermal wraps, hearing aids, ornamental articles such as eye wear, goggles, Col. 18, line 52-67.

(3). As to the components of cross-linked hydrophilic polymer, humectant, water and their contents in the hydrogel adhesive composition in independent claim 14, the disclosure of Coles et al and Brandt et al is incorporated herein as reference. These subject matters mentioned above in applicant's claim 14 have been recited in the applicant's claim 1 and has been discussed in paragraph (2).

. As to the composition of hydrophilic polymer comprising (1) at least 90 mol% of weak acid (2) these weak acid units being from 75 – 95 mol% in acidic form in independent claim 14,

the broad disclosure of Brandt et al meets the limitation by adjusting at least 90 mol% of the weak acids in total mixture of acid group containing monomers for hydrophilic polymer, and about 75 to 95 mol% of weak acid monomers are in acid which is still in the range of at least 25 mol% of acid group containing monomers being in salt form disclosed by Brandt et al.

As to the elastic modulus measured at 25 °C G'_{25}(1 rad/sec) ranging from 1,000 Pa to 10,000 Pa in the independent claim 14, Coles et al disclose as cited: According to the invention there is provided a bioadhesive composition characterized in that it has: (ii) an elastic modules at 1 rad/s of from 700 Pa to 15,000 Pa, Col. 8, line 21-24; Typically the elastic modulus is measured over a range of 0.01-100 rad/s at a given temperature. For skin applications the appropriate temperature is 37 °C, Col. 8, line 34-37. Although the elastic modulus of Coles et al is measured at 37 °C, it would include the range of 1000 Pa – 10,000 Pa if hydrogel adhesive of Cole et al and Brandt et al is measure at 25°C in view of substantially identical polymer, hydrogel compositions disclosed by combined teaching of Coles et al and Brandt et al, and by applicant. Since USPTO does not have proper means to conduct experiments, the burden of proof is now shifted to the applicant to establish the difference. *In re Best,* 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

As to hydrogel adhesive suitable for attachment to mammalian skin in independent claim 14, because the hydrogel adhesive disclosed by combined teaching of Coles et al and Brandt et al is substantially identical to the hydrogel adhesive in the applicant's claim 14, it will be suitable for attachment to mammalian skin as well, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 370 F.2d 576,152 USPQ 235 (CCPA 1967) and In re Otto, 312 F.2d 937,939,136 USPQ 458,459 (CCPA 1963).

As to the limitation of dependent claim 16, the disclosure of Coles et al and Brandt et al is incorporated herein as reference. The most subject matters of humectant comprising glycerol and weak acid monomer units comprising acrylic acid in applicant's claim 16 has been recited in the applicant's claim 3 & 6 and has been discussed in paragraph (2).

As to the limitation of dependent claim 17, Brandt et al disclose as suitable salt-forming cations including alkali metal (Col.7, line 34-35).

As to peel strength on dry skin ranging from 0.3 N/cm to 3.0 N/cm and ratio G"25(1rad/sec)/G' 25(1rad/sec) ranging from 0.15 to 0.65 in dependent claim 18, in view of substantially identical hydrogel composition disclosed by the combined teaching of Coles et al and Brandt et al, and by applicant, it is examiner position to believe that the hydrogel taught by Coles et al and Brandt et al would inherently possess the Peel strength on dry skin ranging from 0.3 N/cm to 3.0 N/cm and same ratio G"25(1rad/sec)/G' 25(1rad/sec) ranging from 0.15 to 0.65. Since USPTO does not have proper means to conduct experiments, the burden of proof is now shifted to the applicant to establish the difference. *In re Best,* 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

Allowable Subject Matter

Claims 9 and 15 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments, see page 5-7 in applicant's Remarks, filed on October 28, 2005, with respect to the rejection(s) of claim(s) 1-18 under 35 U.S.C. 102/103 as anticipated by, or in the alternative, under 35 U.S.C. 103(a) as obvious over Coles et al (US006613030B1) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Coles et al (US006613030B1) and Brandt et al (US004654039).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ives Wu whose telephone number is 571-272-4245. The examiner can normally be reached on 8:00 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Wu can be reached on 571-272-1114. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DAVID W. WU
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1700

Examiner: Ives Wu
Art Unit: 1713
Date: November 28, 2005